REMARKS

This amendment is in response to the Official Action dated May 10, 2011. Claims 1-12, 15, 16, and 41-64 have been rejected over the prior art. The claims have not been amended by the present response

CLAIM REJECTIONS UNDER 35 U.S.C. §112, first paragraph

Claims 1-12, 15, 16, and 41-64 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

In particular, it is alleged on page 2 of the Official Action that claims 1, 41 and 43 fail to comply with the written description requirement because: "Fig. 1B of Applicant's disclosure shows polymer-coated particles held in a matrix 16." This rejection is respectfully traversed.

First, the objections to claims 1, 41 and 43 are based upon a mischaracterization of the disclosure illustrated in Figure 1B. It is alleged that element 16 constitutes a "matrix." This is incorrect. Nowhere is reference element 16 referred to as a matrix in the present specification. Instead, reference element 16 is identified as the implant mass. The implant mass refers to the overall form of the body. Therefore, the lead line associated with reference element 16 contacts only the outer periphery or outline of the implant mass in Figures 1A and 1B of the present application. Therefore, it is entirely incorrect that reference element 16 constitutes a matrix.

Moreover, Figure 1B is a schematic cross-sectional illustration of the embodiment depicted in Figure 1A. As clearly illustrated in Figure 1A, the granules (12) are in intimate contact with one another. Figure 1B simply attempts to schematically illustrate the cross-section of these granules and the implant mass

(16) as a whole. There is absolutely no basis whatsoever in Figure 1B, or its corresponding written description, which supports the contention that claims 1, 41 and 43 fail to satisfy the written description requirement.

As set forth in MPEP §2163, in order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has had possession of the claimed invention. Explicit support for the language of the claims is not a requirement.

The amendments presented in the previous response to claims 1, 42 and 43 are amply supported by the present specification in at least the following locations: paragraphs [0036] ("the granules and polymer are agglomerated to form an implant mass. . ."); [0065]; [0073] ("bonded together"); [0104] (the polymer coated granules "stick together"); and [0105] (the polymer coated granules are stuck together).

Thus, in light of the above, the above noted rejection under 35 U.S.C. §112, first paragraph, is improper and should be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 41-46, 51-55, 63 and 64 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,770,695 to Ricci et al. (hereafter "*Ricci et al.*").

The present invention is directed to compositions which are formulated such that they provide certain advantages and benefits for applications such as a moldable biocompatible implant. Compositions formed according to the principles of the present invention provide certain benefits and advantages relative to conventional biocompatible implant materials.

For example, calcium phosphate cements, which can be biodegradable, have been utilized as biocompatible implants. However, such materials often lead to the formation of dense or solid masses that inhibit osteo-conduction (see, e.g., paragraph [0006]; this is essentially the construction described by *Ricci et al.*). Moreover, implants which are solid and contain only small pores can be disadvantageous in that the natural bone surrounding the implant cannot integrate into the implant unless the implant is degraded. Such degradation processes can take a long time and, at a minimum, delaying the healing process.

A composite implant mass formed according to the principles of the present invention as set forth in claim 41. Claim 41 recites:

> *41. A composite implant mass comprising:*
> *a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules, the granules being regularly-sized, regularly shaped, or spherical, and the granules having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer on at least a portion of each of the granules; and*
> *a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the granules of the implant mass are bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules, and the implant mass is plastically* deformable.

A composite matrix formed according to another aspect of the present invention is set forth in claim 43. Claim 43 recites:

> *43. A composite matrix comprising:*
> *a structural matrix, the structural matrix comprising a plurality of biocompatible synthetic non-polymeric granules bound to each other, at least in part, by adhesion between a biocompatible polymer coating formed on each of the adjacent granules; and*
> *an open porous region comprising macropores between adjacent coated granules;*

> *wherein the structural matrix does not contain any bone particles.*

Ricci et al. clearly fails to anticipate either claims 41 or 43.

Claims 41 requires', *inter alia*, that "the granules of the implant mass are bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules." Similarly, claim 43 requires "a plurality of biocompatible synthetic non-polymeric granules bound to each other, at least in part, by adhesion between a biocompatible polymer coatings formed on each of the adjacent granules." *Ricci et al.* clearly fails to disclose at least these aspects of claims 41 or 43. In fact, the grounds for rejection do not even allege that *Ricci et al.* discloses this. Thus, it is taken as conceded that *Ricci et al.* fails to explicitly disclose at least the above-quoted limitations appearing in claims 41 and 43.

It is alleged on page 6 of the Official Action that:

> It is the Examiner's position that when a plasticizer such as acetone is mixed in with the polymer-coated particles of Ricci et al., some of the particles would be bound by adhesion between the polymeric coatings on the particles.

This assertion is clearly a position of inherency. As set forth in MPEP §2112, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient in order to establish the inherency of that result of characteristic. Instead, in order to satisfy the burden necessary to prove inherency, it must be clear that the missing element or characteristic is necessarily present in the reference, in that it would be recognized as such by persons of ordinary skill. Inherency may also not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

When taken in light of the above stated legal requirements, it is abundantly clear that *Ricci et al.* fails to inherently satisfy the above-quoted limitations of claims 41 and 43.

As evident from the above, the polymer coated granules which are claimed as being in instant contact with one another such that they adhere fits that they are bound to each other by adhesion, are part of a structural component (claim 41) or a structural matrix (claim 43). By contrast, there is no structural component or structural matrix disclosed or suggested by *Ricci et al.* which is not in the form of a dense calcium sulfate matrix within which the polymer coated granules of *Ricci et al.* are disposed. As discussed at length during prosecution of the present application, the particles disclosed in this matrix are not bound to each other by adhesion as required by claims 41 and 43. Therefore, it is irrelevant whether or not, as the Examiner contends, it is necessarily the case, that "some of the particles would be bound by adhesion between the polymer coatings on the particles."

Moreover, no logical explanation or reason is given as to why this must necessarily be the case. There is no explicit disclosure of *Ricci et al.* which would suggest that the particles are stuck together in any fashion at any point in the production of the composite material described therein. Moreover, techniques exist and are readily available to those skilled in the art to prevent such adhesion, such as the use of fluidized beds, etc., to coat the particulates.

In addition, the polymer coating of *Ricci et al.* does not serve to provide adhesion between granules or particles but only to modify the dissolution of calcium sulfate constituting the matrix of the composite material. *Ricci et al.* fails to mention hardening and formation of polymer adhesion by removal of plasticizer (e.g.,

acetone). The plasticizer is used by *Ricci et al.* to manufacture the coating on the granules, and not to condition the polymer layer thereafter so as to form an implant mass, contrary to the purpose of the plasticizer of the presently claimed invention.

For at least the reasons noted above, *Ricci et al.* fails to anticipate either claims 41 or 43. The remaining claims rejected on the above-noted grounds depend from either claim 41 or 43. Thus, these claims are also distinguishable over *Ricci et al.* for at least the same reasons noted above.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-3, 5-9, 11-12, 16, 47-50, and 56-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.*

According to a further aspect of the present invention, a moldable implant mass can be formed according to the aspect set forth in claim 1. Claim 1 recites:

> *1. A moldable implant mass composition for use in repairing a bone defect in a living organism, comprising:*
> *a plurality of biocompatible synthetic non-polymeric granules, said granules having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer coating at least a portion of the implant mass, the implant mass comprising a composite matrix of the granules bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules, and macropores between adjacent granules, so as to form an implant mass comprising a plurality of distinct granules coated with said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass; and*
> *a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.*

As is evident from the above, claim 1 requires, *inter alia*, "a composite matrix of the granules bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules." Claims 41 and 43 contain similar limitations, as discussed above. In the grounds for rejection set forth on page 4 of the Official Action, it is not even alleged that these limitations would have been obvious to one of ordinary skill at the time of the invention in view of *Ricci et al.* Therefore, the grounds for rejection are deficient for at least this reason alone.

Instead of specifically alleging those elements necessary to make out a *prima facie* case of obviousness consistent with the requirements of *Graham v. John Deere*, a one sentence comment is contained on page 6 of the Official Action, as previously explained above, making it clear that while *Ricci et al.* fails to explicitly disclose or satisfy at least the above disclosed or suggest at least the above mentioned elements of claims 1, 41 and 43, these elements are nonetheless inherent to the disclosure of *Ricci et al.* However, for the same reasons explained above in connection with the grounds for rejection on the basis of anticipation by *Ricci et al.*, this is not the case. The comments previously set forth above in connection with the anticipation rejection are incorporated herein by reference. To briefly reiterate, it is abundantly clear that there is no implant mass, structural component, or structural matrix disclosed or suggested by *Ricci et al.* that does not include the pervasive dense calcium sulfate matrix illustrated clearly therein in Figure 1. Therefore, it is irrelevant whether such particles could have stuck together prior to their introduction into said matrix. There is no other explanation given, or reason to believe, that the above-mentioned limitations of claim 1, 41 and 43 must necessarily occur in the composite material of *Ricci et al.* The burden necessary to establish

inherency of the missing feature has clearly not satisfied in the grounds for rejection. Thus, the grounds for rejection are improper and should be withdrawn.

The remaining claims rejected on the above-noted grounds depend either directly or indirectly upon claims 1, 41 and 43. Thus, these claims are also distinguishable over *Ricci et al.* for at least the same reasons noted above.

Claim 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. Patent No. 7,241,316 to Evans et al. (hereafter "*Evans et al.*").

Evans et al. is cited on page 5 of the Official Action as allegedly teaching the use of biocompatible ceramics such as various calcium sulfate salts. However, even if the alleged teachings of *Evans et al.* were to be applied to *Ricci et al.* exactly in the manner suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Evans et al.* clearly fail to satisfy or cure the deficiencies previously noted above possessed by *Ricci et al.* with respect to the requirements of claims 1, 41 or 43. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. Patent No. 7,001,551 to Meredith (hereafter "*Meredith*").

Meredith is applied and set forth on page 5 of the Official Action as allegedly teaching the addition of a biologically active substance. However, even if the alleged teachings of *Meredith* were appropriately applied as set forth in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Meredith* fail to cure the deficiencies previously noted above possessed by *Ricci et*

al. with respect to the requirements of claims 1, 41 or 43. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. Patent No. 4,430,760 to Smestad (hereafter "*Smestad*").

Smestad is cited as allegedly teaching a porous casing or membrane to contain filling material used to repair a bone defect. However, even if the alleged teachings of *Smestad* were to be applied exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, these alleged teachings of *Smestad* clearly fail to cure the deficiencies of *Ricci et al.* discussed above with respect to the requirements of claims 1, 41 or 43. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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